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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,530	07/24/2000	Richard Sackler	200.93185C2C	5659

23280 7590 03/26/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/26/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/624,530

Applicant(s)

SACKLER ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 6-28 are pending.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed January 28, 2002 (Paper No. 10) to the rejection of claims 6-23 made by the Examiner under 35 USC 102 (over 5,133,974) and the judicially created doctrine of double patenting (over Application No. 09/390,719; Application No. 08/938,898; and Application No. 09/304694; Patent No. 5,478,577) have been fully considered and deemed not persuasive.

The Applicant's arguments to the rejection of claims 6-23 made by the Examiner under 35 USC 102 (over 5,968,551; 5,266,331; 5,685,585; and 4,844,909), 103, and the judicially created doctrine of double patenting (over 6,143,322; 5,672,360) have been fully considered and deemed persuasive. Therefore, the said rejections are hereby withdrawn.

Double Patenting Rejection Maintained

The rejection of claims 1-19 under the judicially created doctrine of double patenting over US Patent No. 5,478,577; Application No. 09/390,719; Application No. 08/938,898; and Application No. 09/304694 is MAINTAINED for the reasons set forth in the Office Action mailed October 12, 2001, Paper No. 9, and those found below.

Applicant's remarks regarding the rejection over Application Nos. 09/390719, 08/938,898, and 09/304694 are noted.

Regarding US Patent No. 5,478,577, the Examiner respectfully points out that though the claims do not contain the statements (i) and (ii) (see pg. 2 of response filed 1/28/02), 5,478,577 and the instant Application claim the same controlled-release oral dosage form. Hence, the

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controlled-release oral dosage form of 5,478,577 and the instant invention must have the same properties.

102 Rejection Maintained

The rejection of claims 6-15 and 18-19 under 35 U.S.C. 102(e) as being unpatentable over Paradissis et al. (5,133,974) is MAINTAINED for the reasons set forth in the Office Action mailed October 12, 2001, Paper No. 9, and those found below.

Applicant argues, "no opiod analgesic formulations are exemplified, and it is respectfully submitted that there is no hint or suggestion in this reference of the presently claimed method of treatment having the specified pharmacokinetic parameters". This argument is not persuasive. The Examiner respectfully directs Applicant to claim 2 of the reference, wherein narcotics are disclosed as drugs for use in the invention. The Examiner further points out that morphine, oxycodone and hydromorphone are defined as narcotics in the reference. In regard to the pharmacokinetic parameters, the Examiner respectfully points out that since the opiod analgesic contained in a controlled-release matrix of the reference is the same as that of the instant invention, then the opiod analgesic contained in a controlled-release matrix would have to have the same pharmacokinetic parameters.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing"

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In re Lohr, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 23-35 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant controlled release oral dosage form compared to immediate release oral dosage form. This is seen to be an expected result based on the cited prior art, as it is well established in the art that controlled release oral dosage forms display a peak plasma concentration after a longer period of time, than do immediate release oral dosage forms

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

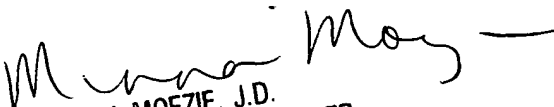
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
March 21, 2002


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600